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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,296	CHU ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *11-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

REQUEST FOR CONTINUED EXAMINATION

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 06/24/04 has been entered.

Applicants' Amendments

2) Acknowledgment is made of Applicants' amendments filed 06/24/2004 and 07/27/04 in response to the final Office Action mailed 06/25/03. With this, Applicants have amended the specification.

Status of Claims

3) Claims 1-3, 5, 6, 8 and 9 have been amended via the amendment filed 06/24/04.

Claim 1 has been amended via the amendments filed 6/24/04 and 07/27/04.

Claims 1-30 are pending.

Claims 1-10 and 27-30 are under examination.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Withdrawn

6) The rejection of claim 3 made in paragraph 7(I) of the Office Action mailed 02/14/03 and maintained in paragraph 23 of the Office Action mailed 06/25/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim..

7) The rejection of claim 3 made in paragraph 24 of the Office Action mailed 06/25/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

8) The rejection of claims 1, 29 and 30 made in paragraph 23 of the Office Action mailed 06/25/03 under 35 U.S.C § 103(a) as being unpatentable over Heo *et al.* (US 6,491,956, already of record) in view of the DE patent 1793631, Shimada *et al.* (US 5,626,837) and Cederholm-Williams (US 2002/0064517 A1), is withdrawn in light of Applicants' amendment to the base claim.

9) The rejection of claims 27 and 28 made in paragraph 28 of the Office Action mailed 06/25/03 under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) or Clements *et al.* (US 6,019,982, already of record) as modified by the DE patent 1793631 and Shimada *et al.* (US 5,626,837, already of record) as applied to claims 1 and 4, and further in view of Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record), is withdrawn.

Rejection(s) Maintained

10) The rejection of claims 1-3, 5, 6, 29 and 30 made in paragraph 26 of the Office Action mailed 06/25/03 under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) in view of the DE patent 1793631 (already of record) and Shimada *et al.* (US 5,626,837, already of record), is maintained for reasons set forth therein and herebelow.

Applicants contend that the central teaching of the primary reference of Casas *et al.* is of a 'vaccine' prepared from live *Lactobacillus* cells that have been transformed to express heterologous 'antigen'. Applicants acknowledge that the use of *Lacobacilli* as a vaccine vehicle for oral vaccination is the context of Casas *et al.* Applicants argue that Casas' disclosure excludes other vaccine vehicles or other forms of antigen delivery. Applicants submit that because Casas relates to *Lactobacillus*, there is arguably, a natural extension to it being added to a milk or milk product for delivery because it is naturally present in milk and milk products, but there is no such 'obvious' connection or extension to other forms of oral vaccination. Applicants state that combining the teaching of Casas to the bactericidic composition of Shimada would therefore be contraindicated. Applicants further assert that Shimada *et al.* does not support DE 1793631, which itself in view of Casas *et al.*, does not render the present invention *prima facie* obvious.

Applicants' arguments have been carefully considered, but are non-persuasive. As

Applicants readily acknowledge, Casas *et al.* disclosed an oral vaccine comprising live *Lactobacillus* cells transformed to express a heterologous antigen. Contrary to Applicants' argument, even if Casas *et al.* excluded other vaccine vehicles or other forms of antigen delivery, Casas *et al.* is still applicable as prior art under 35 U.S.C § 103(a), since instant claims are not limited to 'other vaccine vehicles, or other forms of antigen delivery'. In other words, Casas' oral vaccine expressing a heterologous antigen is not excluded from the scope of Applicants' claims. Instant claims do not exclude other forms of oral vaccination. Contrary to Applicants' contention, the teachings of Casas was not combined with the bactericidic composition of Shimada. Instead, Shimada *et al.* was applied in the rejection to document that the strawberry flavorant such as the one taught by the DE 1793631 patent is water soluble. A yogurt is a palatable substance that serves as a vaccine vehicle. A strawberry-flavored yogurt intrinsically contains a water soluble fruit flavorant. A yogurt comprising Casas' bacterial vaccine serves as an oral vaccine since yogurt is consumed orally and not parenterally.

As set forth in paragraph 26 of the Office Action mailed 06/25/03, Casas *et al.* disclosed a method of vaccinating an animal for beneficially preventing, treating or protecting a diarrhoeal disease comprising administering said animal an orally administered *L. reuteri* vaccine expressing an antigen of enterotoxigenic *E. coli*, for example, K88 *E. coli,* a porcine pathogen. The vaccine is produced by combining the bacterial cells with a pharmaceutically acceptable excipient or a milk, or yogurt vehicle for oral administration. The animal is an avian animal, i.e., inclusive of poultry. The method can be used in pharmaceutical and food industries for vaccination against pathogenic microorganisms. The vaccine is ingested by an animal in a pharmaceutically acceptable carrier or can be added to milk or milk products such as yogurt. See column 5, first full paragraph and lines 40-44; third full paragraph in column 4; column 12, lines 35-43; paragraphs bridging columns 4 and 5, columns 5 and 6, columns 14 and 15, and columns 15 and 16; and Example II.

Casas *et al.* are silent about the presence of a flavorant, such as a strawberry flavorant, in their milk, ice cream or yoghurt vehicle comprising the orally administered vaccine.

However, the use of a strawberry-flavored milk or yoghurt was known and such a product was available in the art at the time of the invention. For example, patent DE 1793631 taught the

routine and conventional addition of a strawberry flavor to ice-cream, yoghurt and milk drinks for the purpose of imparting strawberry taste to these foods. The patent DE 1793631 taught yoghurt and milk drinks containing a strawberry flavoring agent (see abstract). A yogurt is a palatable substance that serves as a vaccine vehicle. A strawberry-flavored yogurt intrinsically contains a water soluble fruit flavorant. A yogurt comprising such a vaccine serves as an oral vaccine since yogurt is consumed orally and not parenterally. That the strawberry flavorant used in the flavored yoghurt and milk drinks described by the patent DE 1793631 is intrinsically water soluble is implicit from the disclosure of the patent in light of what was known in the art. For instance, Shimada *et al.* expressly taught the strawberry flavorant to be water soluble (see claims and Table in columns 11 and 12, particularly line 8 in column 12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace Casas's milk or yoghurt vehicle with the DE 1793631 patented strawberry-flavored milk or yoghurt to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of imparting a strawberry flavor or taste to Casas's oral vaccine contained in milk or yoghurt, since the use of such taste-improving fruit-flavored milk or yoghurt vehicles were well known in the art at the time of the invention as taught by the patent DE 1793631. The Office has clearly established a *prima facie* case of obviousness. The rejection stands.

11) The rejection of claims 1-3, 5, 6, 9, 29 and 30 made in paragraph 27 of the Office Action mailed 06/25/03 under 35 U.S.C § 103(a) as being unpatentable over Clements *et al.* (US 6,019,982, already of record) in view of the DE patent 1793631 (already of record) and Shimada *et al.* (US 5,626,837, already of record), is maintained for reasons set forth therein and herebelow.

Applicants contend that the core teaching of Clements *et al.* is to the use of mLT as an adjuvant with a biologically relevant orally administered antigen and/or vaccine to increase mucosal immune response. Applicants acknowledge that Clements discloses that the vaccinal preparation may be liquid or solid; may be in the form of tablets, capsule, powders, granules, suspension or solutions, or other pharmaceutical vehicle; and may contain any of the other

components in which any of these listed forms of delivery are typical. Applicants state that such a kitchen cabinet type listing/disclosure doe not make obvious the instantly claimed invention. Applicants further submit that the references of Clements *et al.* and Shimada *et al.* provide no suggestion as how this combination leads to the instantly claimed invention.

Applicants' arguments have been carefully considered, but are non-persuasive. As Applicants readily acknowledge, Clements *et al.* disclosed an orally administered liquid vaccine comprising an mLT antigen. Irrespective of whether one views mLT as an antigen, adjuvant or both, Clements' oral vaccine also contained bacterial whole cell antigen. Contrary to Applicants' contention, the combination of the teachings of Clements *et al.* and Shimada *et al.* was not cited as suggesting the instantly claimed invention. Instead, Shimada *et al.* was applied in the rejection to document that the strawberry flavorant is water soluble.

As set forth in paragraph 27 of the Office Action mailed 06/25/03, Clements *et al.* disclosed a method of providing protection against an enterotoxic bacterial pathogen, such as, *Escherichia coli*, by administering an oral vaccine composition comprising the killed or attenuated whole cells (i.e., antigens) of the pathogen and/or a mutant heat-labile enterotoxin. The vaccine comprised a microbial protective antigen such as *Escherichia coli* (a poultry pathogen), *Borrelia burgdorferi* (a canine pathogen), *Clostridium tetani*, *Salmonella typhimurium* (a poultry pathogen), *Brucella suis* (a porcine pathogen), *Leptospira icterohaemorrhagiae, Mycoplasma* sps. or parainfluenza virus, Reo virus, Parvo virus, or respiratory syncytial virus etc., The method is used in birds, immature and mature vertebrates, and animal species. The antigen composition is produced by combining the antigen(s) with a liquid pharmaceutical carrier and *a palatable flavoring agent* for oral administration. The vaccine is further reconstituted with a substance such as milk. See sections 5 and 5.2 of the patent, particularly in columns 9-14 and fifth and sixth full paragraphs in column 4. That Clements' 'birds' are inclusive of poultry and that Clements' 'vertebrates' or 'animal species' are inclusive of swine or dogs is inherent from the teachings of Clements *et al.* since it is well known in the art that Clements' antigens, such as, *Salmonella typhimurium* or *Escherichia coli* are art-known poultry, swine or canine pathogens; *Borrelia burgdorferi* is an art-known canine pathogen; and *Brucella suis* is an art-known swine pathogen.

Clements *et al.* are silent about the presence of a water soluble flavorant, such as a

strawberry flavorant, in their oral vaccine composition reconstituted with milk.

However, the use of a strawberry-flavored milk was known and available in the art at the time of the invention. For example, patent DE 1793631 taught the routine and conventional addition of a strawberry flavor to milk drinks to impart strawberry taste or flavor to the milk. The patent DE 1793631 taught milk drinks containing a strawberry flavoring agent (see abstract). That the strawberry flavorant used in the flavored milk drinks described by the patent DE 1793631 is intrinsically water soluble is implicit from the disclosure of the patent in light of what was known in the art. For instance, Shimada *et al.* taught that the strawberry flavorant is water soluble (see claims and Table in columns 11 and 12, particularly line 8 in column 12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace Clements' milk vehicle with the DE 1793631 patented strawberry-flavored milk to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of imparting a strawberry taste or flavor to Clements' oral vaccine, since the use of such taste-improving fruit-flavored milk vehicle was well known in the art at the time of the invention as taught by the patent DE 1793631. The Office has clearly established a *prima facie* case of obviousness. The rejection stands.

12) The rejection of claims 4 and 7 made in paragraph 28 of the Office Action mailed 06/25/03 under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) or Clements *et al.* (US 6,019,982, already of record) as modified by the DE patent 1793631 (already of record) and Shimada *et al.* (US 5,626,837, already of record) as applied to claims 1 and 4, and further in view of Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record), is maintained for reasons set forth therein and herebelow.

Applicants contend that Grieve does not add to the combination of references already discussed in the prior two rejections without Grieve. Applicants submit that in each case, the rejection posits a view of the art that together lists multiple components and suggests that these components, because they are known in their contexts, make the claimed invention obvious. Applicants state that this selective reading of the art has never been found to form the basis of a proper 103 rejection, absent a direction in the art that leads to the invention. Applicants assert

that that direction or suggestion is absent from Clements and Casaas, is not remedied by Shimada, and is not supplied by Grieve's use of a blue dye.

Applicants' arguments have been carefully considered, but are non-persuasive. As set forth in paragraph 28 of the Office Action mailed 06/25/03, Grieve's reference was not cited for the purpose of showing Grieve's use of a blue dye. Instead, Grieve's reference was applied to document that it was routine at the time of the instant invention to carry out mass vaccination of poultry via drinking water and to further show the presence of motivation to do so, since Grieve expressly taught that the routine mass vaccination of poultry via drinking water is economical and time-effective (see page 28 of Grieve). Therefore, contrary to Applicants' assertion, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to carry out Casas' or Clements' method of providing protection to poultry birds as modified by the DE patent 1793631 and Shimada *et al.* via drinking water vehicle as taught by Grieve to produce the instant invention with a reasonable expectation of success, since Grieve showed it to be conventional, routine, economical and time-effective to administer a vaccine to poultry birds via drinking water. Choosing one art-known administration route or vehicle over another route or vehicle would have been obvious and was well within the realm of routine experimentation. One of skill in the art would have readily understood that administration of a vaccine via drinking water for mass vaccination is a matter of convenience, economy and time effectiveness. Clearly, the Office has established a *prima facie* case of obviousness. The rejection stands.

13) The rejection of claim 10 made in paragraph 29 of the Office Action mailed 06/25/03 under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) or Clements *et al.* (US 6,019,982, already of record) as modified by the DE patent 1793631 (already of record), Shimada *et al.* (US 5,626,837, already of record) and Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record) as applied to claims 1, 6 and 7, and further in view of Roland (US 6,399,074, already of record), is maintained for reasons set forth therein and herebelow.

Applicants contend that the addition of Roland adds no disclosure teaching that makes obvious how the addition of a flavorant to a syringe administered oral vaccine, makes obvious

claimed method of providing protection against disease. Applicants state that it is yet another reference that merely lists something in common with a feature of the claimed invention, but does not teach or suggest to one skilled in the art the invention defined by claim 10.

Applicants' arguments have been carefully considered, but are non-persuasive. As set forth in paragraph 29 of the Office Action mailed 06/25/03, Roland's reference is applied to document that it was routine at the time of the instant invention to use a syringe for oral administration or vaccination of birds (see lines 20-22 in column 18 of Roland). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to carry out Casas' or Clements' method as modified by the DE patent 1793631, Shimada *et al.* and Grieve in poultry using Roland's feeding syringe to produce the instant invention with a reasonable expectation of success, since Roland has shown it to be conventional and routine to administer a vaccine orally to birds using a syringe. Choosing one art-known administration method over another would have been obvious and is well within the realm of routine experimentation. One of skill in the art would have readily understood that oral administration of a vaccine using a syringe is a matter of convenience. Clearly, the Office has established a *prima facie* case of obviousness. The rejection stands.

14) The rejection of claim 8 made in paragraph 30 of the Office Action mailed 06/25/03 under 35 U.S.C § 103(a) as being unpatentable over Clements *et al.* (US 6,019,982, already of record) as modified by the DE patent 1793631 (already of record), Shimada *et al.* (US 5,626,837, already of record) and Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record) as applied to claims 1, 6 and 7, and further in view of Frantz *et al.* (US 5,536,496, already of record), is maintained for reasons set forth therein and herebelow.

Applicants contend that the citation of a reference, Frantz, to identify a particulate antigen does not make obvious the invention defined by the method of claim 8. Applicants state that the Frantz teaching of a new *P. multocida* protein or that it can be combined with *E. rhusiopathiae* antigen hardly qualifies as a teaching motivating the production of the invention. Applicants allege that this amounts to hindsight, and equates the disclosure of any specific component in the art in general with motivation. Applicants submit that motivation and the suggestion to combine

to arrive at the invention claimed, must be shown to come from the references. Applicants further allege that the rejection fails to make the *prima facie* case.

Applicants' arguments have been carefully considered, but are non-persuasive. As set forth in paragraph 30 of the Office Action mailed 06/25/03, the reference of Frantz was applied to document that Frantz *et al.* disclosed an *Erysipelothrix rhusiopathiae* bacterin or vaccine which is administered by any mode of administration or by any suitable route. The vaccine protected pigs from a challenge infection. See columns 20 and 21; see first full paragraph in column 5; and paragraph bridging columns 5 and 6 of Frantz *et al.* Furthermore, Clements *et al.* also taught that their vaccine may contain and be administered with any biologically relevant antigen and/or vaccine, or killed or attenuated pathogens or relevant virulence determinants (i.e., antigens) of specific pathogens (see paragraph bridging columns 9 and 10; and paragraph bridging columns 11 and 12 of Clements *et al.*). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Frantz's *Erysipelothrix rhusiopathiae* bacterin or protective vaccine in Clements' method as modified by the DE patent 1793631, Shimada *et al.* and Grieve to produce the instant invention with a reasonable expectation of success, since Clements *et al.* expressly taught that any biologically relevant antigen and/or vaccine, or killed or attenuated pathogens or relevant virulence determinants (i.e., antigens) of a specific pathogen can be used in their method. Given the teaching of Frantz *et al.* that their *Erysipelothrix rhusiopathiae* bacterin or protective vaccine is administered by any mode of administration or by any suitable route, one of skill in the art would have been motivated to produce the instant invention for the expected benefit of additionally providing protection against *Erysipelothrix rhusiopathiae* disease in pigs or immature piglets. Clearly, the motivation or the suggestion did not come from the specification. The Office has established a *prima facie* case of obviousness. The rejection stands.

Rejection(s) under 35 U.S.C. 112, First Paragraph (New Matter)

15) Claims 1-10 and 27-30 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1, 2, 5, 6, 8 and 9 include the limitation: 'nonhuman'. However, there appears to be no descriptive support in the specification, as originally filed, for the limitation. Instead, at lines 19-21 on page 5 of the specification, Applicants specifically include within the scope of the invention an 'animal handler', such as, a farm worker, veterinarian etc., Therefore, the above-identified limitation in the claims is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. 112, Second Paragraph

16) Claims 1-10 and 27-30 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague, indefinite, confusing and/or lacks proper antecedence in the recitation 'protection against a disease' (see last line), because it is unclear whether or not the protection provided is against --the-- same disease as the one recited in line 1 of the claim.

(b) Claim 2 is vague and confusing in the recitation 'antigen is capable of causing a disease'. Claim 2 depends from claim 1 which is drawn to a 'method of providing protection against a disease'. It is unclear whether the purpose of the claimed method is to provide protection against a disease as claimed in the independent claim 1, or whether the purpose is to cause disease by administering the antigen-containing oral vaccine as claimed in claim 2.

(c) Claim 3 is confusing in the incorrectly spelled recitations: '*hyopneumonia*' (see line 3); '*Leptspira*' (see line 5); '*Clostridium tetanus*' (see line 9); '*Sepullina*' (see line 17); and '*rhinotrachelitis*' (see line 23). Correction is requested.

(d) Claim 10 is redundant and/or has improper antecedence in the recitation: 'the administration of the orally administered vaccine'. For clarity and definiteness, it is suggested that Applicants replace the recitation with --the administration of the oral vaccine--.

(e) Claim 7 is incorrect, redundant and/or has improper antecedence in the recitation: 'the administration of the orally administered vaccine is a mass administration'. For clarity and definiteness, it is suggested that Applicants replace the recitation with --the administration of the oral vaccine is by mass administration--.

(f) Claim 3 is incorrect, indefinite and/or confusing in the limitation: 'antigen' is selected from the group consisting of .... 'Swine pox .... Infectious bursal disease, Infectious bronchitis, ... Turkey rhinotracheltis, Cauidiosis, ... Canine Parainfluenza, ... Canine Rabies, ... Feline rhinotrachelitis, Feline Panleukopenia, and Feline rabies', because these represent clinical or medical conditions or diseases as opposed to specific bacteria or virus causing the condition or disease. It is unclear how an 'antigen' can be selected from a disease, as opposed to a bacterium or virus causing the disease.

(g) Claim 27 is confusing and vague in the limitation: 'fruit flavorant is selected from the group consisting of cherry, grape, watermelon, and apple'. Cherry, grape, watermelon and apple are fruits as opposed to fruit flavorants. For clarity and definiteness, it is suggested that Applicants replace the phrase with --fruit flavorant is selected from the group consisting of cherry flavorant, grape flavorant, watermelon flavorant and apple flavorant--..

(h) Analogous criticism applies to claims 28 and 30.

(I) Claims 2-10 and 27-30, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. 103

17) Claims 1-7, 9 and 28-30 are rejected under 35 U.S.C § 103(a) as being unpatentable over Brinton *et al.* (WO 99/59626) in view of Strobel *et al.* (US 6,225,304 B1) and Collins *et al.* (US 6,498,008).

The references of Strobel *et al.* and Collins *et al.* are applied in this rejection since the references qualify as prior art under 35 U.S.C § 102(e), and accordingly are not disqualified under 35 U.S.C § 103.

Brinton *et al.* disclosed a method of immunizing (i.e., providing protection against a disease) poultry by mass administration of an oral vaccine composition comprising an inactivated bacterial antigen to poultry, pigs or cattle via drinking water vehicle (see abstract; first and fourth

paragraphs on page 3; page 23; and paragraph bridging pages 3 and 4). The vaccine is a bacterin of *E. coli*, *Bordetella avium*; *Pasteurella multocida*; and *Ornithobacterium rhinotropicale* (see claims 13-20; page 13; and Examples, particularly Examples 4 and 5). The prior art method includes the step of admixing the bacterin antigen with a vehicle suitable for oral administration of the vaccine, such as, drinking water (see Examples).

Brinton *et al.* do not teach the step of admixing a water soluble palatable fruit flavorant, fish flavorant, or meat flavorant with the drinking water vehicle containing the bacterial antigen or vaccine.

However, Strobel *et al.* showed the routine and conventional nature of flavoring an animal's drinking water. Strobel *et al.* explicitly taught enhancing the palatability of animals' drinking water by adding a flavor such as strawberry flavor or licorice flavor. Strobel *et al.* disclosed that such flavored water can be fed to all forms of domestic animals or livestock, such as, pigs, cattle, poultry especially chickens and turkeys, horses, sheep, dogs, cats and the like. See second and third full paragraphs in column 5; and Examples 1-3.

Collins *et al.* expressly taught or suggested that vaccine solutions can be suitably flavored by various known agents to promote the uptake of the vaccine orally by animals (non-human) such as pigs (see last full paragraph in column 5).

Given Collins' express suggestion, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include Strobel's step of adding a palatable strawberry flavor to Brinton's drinking water vehicle that comprises the bacterial antigen-containing oral vaccine to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention by suitably flavoring Brinton's oral composition by adding Strobel's palatable strawberry flavor for the expected benefit of favorably promoting the uptake of Brinton's oral vaccine by animals as taught by Collins *et al.*

Claims 1-7, 9 and 28-30 are *prima facie* obvious over the prior art of record.

18) Claim 27 is rejected under 35 U.S.C § 103(a) as being unpatentable over Brinton *et al.* (WO 99/59626) as modified by Strobel *et al.* (US 6,225,304 B1) and Collins *et al.* (US 6,498,008) as applied to claims 7 and 1 above, and further in view of Mitani *et al.* (JP 02163064

A).

The teachings of Brinton *et al.* as modified by Strobel *et al.* and Collins *et al.* are explained above, which do not disclose the palatable flavorant being an apple flavorant.

However, the step of adding an alternate fruit flavor, such as, an apple flavor to drinking water was well known in the art at the time of the invention. For example, Mitani *et al.* taught the use of apple flavor to flavor drinking water (see abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace Strobel's palatable strawberry flavorant in Brinton's drinking water vehicle that comprises the bacterial antigen-containing oral vaccine with Mitani's apple flavorant to produce the instant invention, with a reasonable expectation of success, since Mitani *et al.* taught that drinking water can be flavored with an apple flavor. The replacement of one fruit flavor with another alternate fruit flavor would have been a matter of choice of flavor. Substitution of one fruit flavorant with another alternate fruit flavorant is well within the realm of routine experimentation, would have been obvious to one of skill in the art, and would have similarly promoted the uptake of the vaccine-containing drinking water, absent evidence to the contrary.

Claim 27 is *prima facie* obvious over the prior art of record.

19) Claim 10 is rejected under 35 U.S.C § 103(a) as being unpatentable over Brinton *et al.* (WO 99/59626) as modified by Strobel *et al.* (US 6,225,304 B1) and Collins *et al.* (US 6,498,008) as applied to claims 7 and 1 above, and further in view of Roland (US 6,399,074, already of record).

The reference of Roland is applied in this rejection because it qualifies as prior art under subsection (e) of 35 U.S.C § 102 and accordingly is not disqualified under U.S.C 103(a).

The teachings of Brinton *et al.* as modified by Strobel *et al.* and Collins *et al.* are explained above, which do not disclose the administration of the vaccine into the mouth through a syringe.

However, it was routine at the time of the instant invention to use a syringe for oral administration in or vaccination of birds. For instance, Roland taught such a routine procedure (see lines 20-22 in column 18).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to carry out Brinton's method as modified by Strobel *et al.* and Collins *et al.* in poultry using Roland's feeding syringe to produce the instant invention with a reasonable expectation of success, since Roland has shown it to be conventional and routine to administer a vaccine orally to birds using a syringe. Choosing one art-known administration method over another would have been obvious and is well within the realm of routine experimentation. One of skill in the art would have readily understood that oral administration of a vaccine using a syringe is a matter of convenience.

Claim 10 is *prima facie* obvious over the prior art of record.

20) Claims 1-8 and 28-30 are rejected under 35 U.S.C § 103(a) as being unpatentable over Bricker *et al.* (*Avian Diseases* 32: 668-673, 1988) in view of Strobel *et al.* (US 6,225,304 B1) and Collins *et al.* (US 6,498,008).

The references of Strobel *et al.* and Collins *et al.* are applied in this rejection since the references qualify as prior art under 35 U.S.C § 102(e), and accordingly are not disqualified under 35 U.S.C § 103.

Bricker *et al.* taught a method of providing protection against erysipelas in turkeys comprising admixing an *Erysipelothrix rhusiopathiae* vaccine (i.e., antigen) with drinking water and administering the vaccine orally to turkeys (see abstract; 'Materials and Methods' and 'Results').

Bricker *et al.* do not teach the step of admixing a water soluble palatable fruit flavorant, fish flavorant, or meat flavorant with the drinking water vehicle containing the bacterial antigen or vaccine.

However, Strobel *et al.* showed the routine and conventional nature of flavoring an animal's drinking water. Strobel *et al.* explicitly taught enhancing the palatability of animals' drinking water by adding a flavoring such as strawberry flavor or licorice flavor. Strobel *et al.* disclosed that such water can be fed to all forms of domestic animals or livestock, such as, pigs, cattle, poultry especially chickens and turkeys, horses, sheep, dogs, cats and the like. See second and third full paragraphs in column 5; and Examples 1-3.

Collins *et al.* expressly taught or suggested that vaccine solutions can be suitably flavored

by various known agents to promote the uptake of the vaccine orally by animals (see last full paragraph in column 5).

Given Collins' express teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include Strobel's step of adding a palatable strawberry flavor to Bricker's drinking water vehicle that comprises the *Erysipelothrix rhusiopathiae* oral vaccine to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention by suitably flavoring Bricker's oral composition by adding Strobel's palatable strawberry flavor for the expected benefit of favorably promoting the uptake of Bricker's *Erysipelothrix rhusiopathiae* oral vaccine as taught by Collins *et al.*

Claims 1-8 and 28-30 are *prima facie* obvious over the prior art of record.

Objection(s)

21) Claims 2 and 3 are objected to for the following reasons:

(a) Claim 2 is objected to for lacking a comma in between the limitation: 'sheep goats'.

(b) Claim 3 is objected to for lacking a space in between the limitation: '*Salmonellacholeraesuis*'.

(c) The claims are objected to because the lines are crowded too closely together, making reading and entry of amendments difficult. Substitute claims with lines one and one-half or double spaced are required. See 37 CFR 1.52(b). In the instant case, in light of the underlining and strike-through lining used in amended versions of claims, it is strongly suggested that Applicants submit claims in future with at least 1.5 space between the lines.

Remarks

22) Claims 1-10 and 27-30 stand rejected.

23) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The RightFax number for submission of amendments or other papers is (703) 872-9306.

24) Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

25) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2004

S. DEVI, PH.D.
PRIMARY EXAMINER